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## **ISK-BIOTECH**

August 4, 1992

Andy Ertman
Document Processing Desk (RS-0097)
Office of Pesticide Programs (H7508W)
Special Review and Reregistration Division
U.S. Environmental Protection Agency
Room 266A, Crystal Mall No. 2
1921 Jefferson Davis Highway
Arlington, VA 22202

Dear Mr. Ertman:

Subject:

ROTATIONAL CROP DATA REQUIREMENT (EPA GUIDELINE NO. 174-A-SS)

CHLOROTHALONIL DATA CALL-IN

(Chemical #081901, Case #0097)

Dated July 31, 1991 & Received August 5, 1991

Reference Petition No. 2E4050 for Exemption from Tolerance Reference Federal Register, Vol. 57, June 10, 1992, Page 244552

The Chlorothalonil Data Call-In (DCI) requires submission of data to satisfy EPA Guideline No. 174-A-SS, Rotational Crops. The purpose of this letter is to identify data previously submitted and actions resulting from the Agency's review of those data. Thus, this data requirement should be satisfied and no additional data should be required relative to ISK Biotech's products. However, other registrants should offer to pay compensation before they can amend their labels.

On September 24, 1991 ISK Biotech submitted a petition for exemption from tolerances (Petition No. 2E4050) for the following soil metabolites of chlorothalonil:

## 3-Carbamyl-2,4,5-trichlorobenzoic acid (SDS-46851)

SDS-46851 is a minor degradation product of chlorothalonil formed only in the soil. It is not a product of plant or animal metabolism of chlorothalonil and is not a manufacturing impurity. Although only low levels of SDS-46851 have been found in soil following application of chlorothalonil to crops, it is taken up by some rotated crops in some environments.

## 4-Hydroxy-2-5,6-trichloroisophthalonitrile (SDS-3701)

SDS-3701 is the major soil degradate of chlorothalonil and also may be a product of plant and animal metabolism of chlorothalonil. SDS-3701 is currently included in tolerance expressions for chlorothalonil. The petition sought to exempt SDS-3701 in rotated crops from tolerances, since it has been demonstrated that significant residues of SDS-3701 do not occur in rotated crops.

IMPORTANT NOTE: After review, the petition was amended to exempt only SDS-46851, as the Agency determined that significant residues of SDS-3701 are not expected to be present in rotated crops.

Andy Ertman August 4, 1992

Concurrent with the submission of the Petition, applications were also submitted for amended registration for each of the following end-use chlorothalonil products used for agricultural purposes:

Name of Product	EPA Reg. No.		
BRAVO 500	50534-8		
BRAVO W-75	50534-23		
BRAVO 90DG	50534-157		
BRAVO S	50534-159		
BRAVO 720	50534-188		
CHLOROTHALONIL 75 WP	50534-189		

The petition and applications were submitted to Ms. Cynthia Giles-Parker (PM-22), Registration Division. The applications requested deletion of the rotational crop restriction imposed by the 1984 Chlorothalonil Registration Standard, which read as follows:

Note to User: Do not rotate to crops other than those listed on labels within 12 months of the last treatment. After 12 months from the last application, leafy vegetables (i.e. spinach, lettuce, kale, etc.) may also be rotated.

Attached is a copy of the Agency's final rule published June 10, 1992 in the Federal Register, Page 24552. Also a copy of the proposed rule is enclosed (FR. April 15, 1992; Page 13073-4). A copy of EPA's letter dated June 4, 1992 and accepted labeling for BRAVO 720 (EPA Reg. No. 50534-188) are also enclosed as representative of the Agency's acceptance of labeling which removes the rotational crop restriction from BRAVO labels.

Studies which should be considered as satisfying rotational crop data requirements include the following MRID Numbers:

00139550	00156477	41564819	41564820	41564821	41564822
41564823	41564824	41564825	41564826	41564827	41564832
41564833	41564834	41564835	41564836	41564837	41564838
41564839	41564840	41564841	41564842	41564843	41564844
41564845	41564846	41364841 42090109	41304842	41304643	41204044

In addition to the rotational crop studies supporting the petition, appropriate toxicology studies were also submitted.

I trust that the Agency will recognize that the rotational crop data requirements have been fully satisfied through data supporting the above actions and that no additional crop rotation data are required for chlorothalonil.

Sincerely yours,

Ralph P. Burton

Manager Product Registrations

Attachments: 4